AUG 1 9 2002

510(k) Summary

as required by 807.92

K021738

1. Company Identification

Totoku Electric Co., Ltd.
300 Oya, Ueda-shi, Nagano-ken, 386-0192, JAPAN
Tel: 011-81-268-34-5484
Fax: 011-82-268-34-5565

2. Official Correspondent

Mikio Hasegawa (Mr.)
General Manager
Product Development Dept.

3. Date of Submission

May 24, 2002

4. Device Trade Name

Flat Panel Displays, ME Series and CCL Series

5. Common Name

Monitor, display, workstation, and others

6. Classification

Medical displays were classified in Class II per 21 CFR 890.2050

7. Predicate Device

Totoku ME311L 3Mega Pixel Diagnostic Display, manufactured by Totoku Electric Co., Ltd. (K012099). Comparison of the principal characteristics of the one device which is pertinent to clinical performance is shown in Appendix 1.

8. Description of Device

The ME and CCL Series Medical Displays are displays for medical use.

9. Intended Use

The ME and CCL Series Medical Displays are intended for use with Picture Archiving Communication Systems (PACS) for medical imaging applications by physicians.

10. Explanation of ME Series and CCL Series

ME Series are monochrome LCD displays consists of the following models.

ME181L (Model No. MDL1809A)

ME201L (Model No. MDL2006A)

ME203L (Model No. MDL2004A)

CCL Series are color LCD displays consists of the following models.

CCL182 (Model No. CDL1808A)

CCL202 (Model No. CDL2005A)

CCL314 (Model No. CDL2103A)

Comparison of specifications are shown in Appendix 2.

11. Compliance standards

All ME Series are complies with following standards.

Medical Safety: UL2601-1, CSA No. 601-1, IEC60601-1
MDD/CE (EN60601-1)

EMC: MDD/CE (EN60601-1-2), IEC60601-1-2, FCC-B and VCCI-B for ME181L (MDL1809A) and ME201L (MDL2006A).
MDD/CE (EN60601-1-2), IEC60601-1-2, FCC-A and VCCI-A for ME203L (MDL2004A)

All CCL Series are complies with following standards.

ITE Safety: UL1950, CSA No.950, LVD/CE(EN60950)

EMC: EMC/CE (EN55022, EN55024), FCC-B and VCCI-B for CCL182 (CDL1808A) and CCL202 (CDL2005A).
EMC/CE (EN55022, EN55024),FCC-A and VCCI-A for CCL314 (CDL2103A).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2002

Mr. Mikio Hasegawa
General Manager
Totoku Electric Co., Ltd.
Product Development Dept.
MM Company
300 Oya, Ueda-Shi,
Nagano 386-0192
JAPAN

Re: K021738
Trade/Device Name: Medical Flat Panel Displays, ME and CCL Series
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 24, 2002
Received: May 28, 2002

Dear Mr. Hasegawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

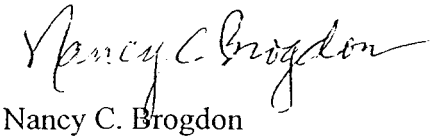
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): ~~Not known~~ K021738

Device Name: Flat Panel Display, ME and CCL Series

Indications for Use:

The ME and CCL Series Medical Displays are intended for use with Picture Archiving Communication Systems (PACS) for medical imaging application by physicians.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021738

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)